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Carrara, Marco; Yakar, Derya; Kasalak, Ömer; Kwee, Thomas C

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A new complication registration system for errors in radiology: Initial 5-year experience in a tertiary care radiology department

Marco Carrara, Derya Yakar, Ömer Kasalak, Thomas C. Kwee*

Medical Imaging Center, Department of Radiology, Nuclear Medicine and Molecular Imaging, University of Groningen, University Medical Center Groningen, the Netherlands

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ABSTRACT

Purpose: To describe and evaluate our initial 5-year experience with a new complication registration system for errors in radiology.

Materials and methods: This study reviewed all cases that were submitted to a new complication registration system of a tertiary care radiology department between 2015–2019.

Results: Sixty-seven cases were included. In the group of diagnostic complications/errors (n = 34), there were 21 perceptual errors and 13 cognitive errors. This 61.8 % (21/34) perceptual error rate was not significantly different ($P = 0.297$) from the 70 % perceptual error rate known from previous literature. In the group of interventional complications (n = 19), most cases (47.4 % [9/19]) concerned symptomatic or major hemorrhage. In the group of organizational complications/errors (n = 14), the leading incident type according to the International Classification System for Patient Safety was clinical process/procedure with wrong body part/side/site as subclassification (35.7 % [5/14]). Harm severities were none (n = 35), mild (n = 10), moderate (n = 10), severe (n = 6), death (n = 5), and unknown (n = 1). Harm severity of interventional complications was significantly higher ($P < 0.05$) than that of organizational complications, while there were no significant differences in harm severities between other groups of complications.

Conclusion: It is feasible to implement the radiologic complication registration system that was described in this study. Perceptual mistakes, hemorrhage, and procedures on the wrong body part/side/site dominated in the categories of diagnostic, interventional, and organizational complications/errors, respectively, and these should be the topic of vigilance in clinical practice and further research. Future studies are also required to determine whether this complication registration system reduces radiologic errors and improves healthcare quality.

1. Introduction

Hospital systems operate in complex and high-risk environments, in which the risk of error is high [1]. Errors have been reported to cause an estimated 251,454 deaths in hospitals in the United States each year, and to rank third after cancer and heart disease as the leading cause of death [2]. Error has also been recognized as a frequent occurrence in diagnostic radiology for many decades [1]. The retrospective error rate among radiologic examinations has been reported to be approximately 30 %, with real-time errors in daily radiology practice averaging 3–5 % [3,4]. While the diagnostic error rate for radiologists is lower than that of other specialties [5,6], the frequency of errors in interventional radiology has been shown to be comparable to that in the surgical disciplines [7]. Current philosophy recognizes that conditions for error are constantly present in healthcare because they are inherent in the endeavor itself [1]. Thus, the goal is not to eliminate human error but to develop strategies to prevent, identify, and mitigate errors and their effects before they result in harm [1].

Within this context, the concept of a new complication registration system was introduced by the Dutch Society of Radiology in the Netherlandsin 2015 [8]. Individual radiology departments are encouraged to employ this system in which complications related to errors in diagnostic and interventional procedures, and due to organizational circumstances, are registered [8]. Complication cases are collected, anonymized, and presented and discussed by radiologists and residents in a formal one-hour bi-annual meeting [8]. The aim of such a

Abbreviations: CT, computed tomography; US, ultrasonography; ICPS, International Classification for Patient Safety; WHO, World Health Organization; MRI, magnetic resonance imaging

* Corresponding author at: Department of Radiology, Nuclear Medicine and Molecular Imaging, University Medical Center Groningen, University of Groningen, Hanzeplein 1, P.O. Box 30.001, 9700 RB Groningen, the Netherlands.

E-mail address: thomaskwee@gmail.com (T.C. Kwee).

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complication registration system is to learn from the errors made, and to reduce the severity and frequency of future errors, thereby improving the overall quality of patient care [8].

The new complication registration system has been adapted by our tertiary care radiology department immediately after its conception and recommendation for clinical use in 2015. However, this system has not been formally described and evaluated yet in the international literature. This may stimulate dissemination of this potential error reduction strategy to other institutions, and may provide valuable insight into the spectrum of errors that are encountered in diagnostic and interventional radiology from which lessons can be learned.

The purpose of this study was therefore to describe and evaluate our initial 5-year experience with a new complication registration system for errors in radiology.

2. Materials and methods

2.1. Study design

The local institutional review board approved this retrospective study, and the requirement for informed consent was waived. The University Medical Center Groningen is a tertiary care center that serves more than 2 million people in the north-east of the Netherlands. All cases that were submitted to the complication registration system of the department of radiology of the University Medical Center Groningen between June 2015 and September 2019, were eligible for inclusion. Cases were excluded if they were too poorly reported to understand the nature of the complication, or if they were not related to any procedure that was performed at the department of radiology.

2.2. Definition of complications

A diagnostic complication is defined as a wrong interpretation of a diagnostic radiology examination with a negative impact on patient's health to such an extent that it requires a change in patient management or that it involves irreparable damage to health (8). Examples of diagnostic complications are failure to detect localized lung cancer on computed tomography (CT) that is not timely treated and develops into incurable metastatic disease, or false-positive diagnosis of appendicitis on ultrasonography (US) that is followed by unnecessary surgery. An interventional complication is defined as an unintended or undesired event or situation during or within 30 days following an interventional radiology procedure, with a negative impact on patient's health to such an extent that it requires a change in patient management or that it involves irreparable damage to health [8]. An example of an interventional complication is an intestinal perforation during US-guided abscess drainage that requires additional treatment and/or a longer hospital stay. An organizational complication is defined as an unintended or undesired organizational or logistic event or situation with a negative impact on patient's health to such an extent that it requires a change in patient management or that it involves irreparable damage to health [8]. An example of an organizational complication is lack of adequate communication of a critical finding on an imaging examination to the referring physician, as a result of which no appropriate action is taken and disease progression occurs (e.g. a pulmonary nodule that develops into metastatic lung cancer). Diagnostic, interventional, and organizational errors without any harmful consequences to the patient are not considered a complication, but are also eligible for registration [8]. An example of a diagnostic error without harmful consequences is a fracture that is missed by the radiologist but that is timely detected and treated by the referring physician.

2.3. Complication registration system

In line with the recommendation and guidelines of the Dutch Society of Radiology [8], diagnostic, interventional, and organizational complications, and errors without any harmful consequences to the patient, are registered by the department of radiology of the University Medical Center Groningen. One radiologist has a permanent position as the coordinator of the complication registration system [8]. All radiologists and residents (averaging around 55 people in our department at any time) are aware of the complication registration system and the encouraging policy of the department to submit all cases to this coordinator [8]. Cases are submitted to the coordinator without the use of a structured reporting form. This submission process is on a voluntary basis [8]. Submitted cases are anonymized and prepared by the coordinator for presentation and discussion in a formal one-hour bi-annual meeting [8]. All radiologists and residents are obliged to attend this closed meeting [8]. Causes and circumstances under which each complication occurred and if they could be prevented, are discussed [8]. The minutes of the meeting are recorded by the coordinator, along with an improvement plan and action points (when applicable) [8]. A general overview of the complication registration is included in the department's annual report [8].

2.4. Classification of complications

Diagnostic complications and diagnostic errors without any harmful consequences to the patient were first categorized as either perceptual errors (i.e. detection errors) or cognitive (interpretive) errors (i.e. decision errors in the perception of an abnormality) [9]. They were also classified according to the system proposed by Kim and Mansfield (Table 1) [10]. Interventional complications were descriptively reported given the lack of a specific classification system for this purpose [11]. Organizational complications were classified according to the International Classification System for Patient Safety (ICPS), which comprises 13 main incident types: clinical administration, clinical process/procedure, documentation, healthcare-associated infection,

Table 1
Classification of errors in diagnostic radiology (adapted from [10]).

Type	Cause of error	Explanation
1	Complacency	Error of overreading and misinterpretation, in which a finding is appreciated but is attributed to the wrong cause
2	Faulty reasoning	Error of overreading and misinterpretation, in which a finding is appreciated and interpreted as abnormal but is attributed to the wrong cause. Misleading information and a limited differential diagnosis are included in this category
3	Lack of knowledge	The finding is seen but is attributed to the wrong cause because of a lack of knowledge on the part of the viewer or interpreter
4	Underreading	The finding is missed
5	Poor communication	The lesion is identified and interpreted correctly, but the message fails to reach the clinician
6	Technique	The finding is missed because of the limitations of examination or technique
7	Prior examination	The finding is missed because of failure to consult prior radiologic studies or reports
8	History	The finding is missed because of acquisition of inaccurate or incomplete clinical history
9	Location	The finding is missed because of the location of a lesion outside the area of interest on an image, such as in the corner of an image
10	Satisfaction of search	The finding is missed because of failure to continue to search for additional abnormalities after the first abnormality was found
11	Complication	Complication from a procedure
12	Satisfaction of report	The finding was missed because of complacency of report, and overreliance of the radiology report of the previous examinations

Table 2
Overview of all 34 diagnostic complications/errors that were included in this study, according to the system proposed by Kim and Mansfield [10], organ system/subspecialty, imaging modality, and harm severity according to the WHO's definition [13].

Type / cause of error [10]	No. of cases	Organ system / subspecialty (no.)	Imaging modality (no.)[a]				Harm severity (no.) [13]
			X-ray	US	CT	MRI	
1. Complacency	1	Musculoskeletal (1)			1		None (1)
2. Faulty reasoning	8	Abdomen (3) Cardiothoracic (2) Musculoskeletal (3)	3	2	2	4	None (7) Death (1)
3. Lack of knowledge	0						
4. Underreading	14	Abdomen (10) Musculoskeletal (4)	2		8	4	None (12) Death (1) Unknown (1)
5. Poor communication	3	Abdomen (1) Cardiothoracic (1) Musculoskeletal (1)			2	1	None (2) Moderate (1)
6. Technique	0						
7. Prior examination	0						
8. History	1	Cardiothoracic (1)	1				Severe (1)
9. Location	2	Neuro (1) Head-neck (1)			1	1	None (2)
10. Satisfaction of search	4	Abdomen (1) Breast (1) Musculoskeletal (1) Neuro (1)			2	2	None (4)
11. Complication	0						
"04" Satisfaction of report	1	Abdomen (1)		1			Moderate (1)

Abbreviations: CT: computed tomography. MRI: magnetic resonance imaging. US: ultrasonography.
[a] One case can involve multiple imaging modalities.

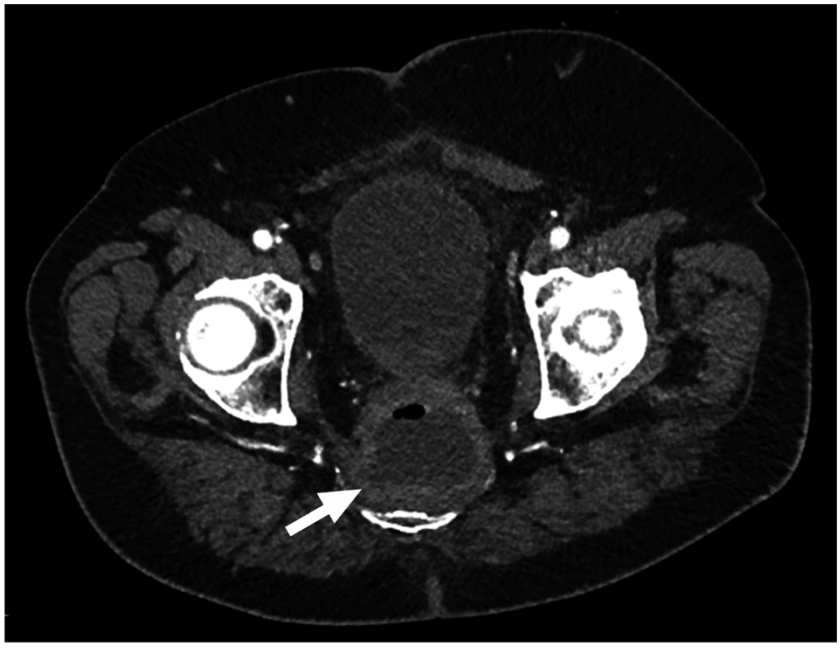

Fig. 1. A 65-year-old man with a history of rectal cancer and low anterior resection, and a recent diagnosis of acute myeloid leukemia, presented with a cold and blue digit I of the left foot. CT of chest, abdomen and legs was performed to screen for intravascular thrombi. The radiologist who interpreted the CT scan reported a possible occlusion of the left dorsalis pedis artery, but missed the presacral abscess (arrow). Two weeks later the abscess was detected on another CT scan that was made because of clinical deterioration with elevated blood infection parameters. Because of the patient's clinical condition, palliative therapy was initiated and the patient deceased one day after the last CT scan.

medication/IV fluids, blood/blood products, nutrition, oxygen/gas/vapor, medical device/equipment, behavior, patient accidents, infrastructure/building/fixtures, resources/organizational management [12]. Level of harm of each complication was classified according to the World Health Organization (WHO)'s definitions as none, mild, moderate, severe, or death [13].

2.5. Statistical analysis

In the group of diagnostic complications/diagnostic errors, perceptual errors have previously been reported to outnumber cognitive errors, with around 70 % attributable to the former [13]. To test the hypothesis that an equal percentage of perceptual errors was submitted to the complication registration system, a general *Z*-test was performed to compare the rate of perceptual errors in the present study to the 70 % that was previously reported in the literature [13]. To test the hypothesis that patient harm was more severe for interventional complications than for diagnostic and organizational complications, a Kruskal-Wallis analysis with post-hoc Conover tests was performed. *P*-values less than 0.05 were considered statistically significant. Statistical analyses were performed using MedCalc version 19.1.6 software (MedCalc, Mariakerke, Belgium).

Table 3
Overview of all 19 interventional complications that were included in this study, including description, interventional procedure, type of imaging guidance, and harm severity according to the WHO's definition [13].

Description of complication	No. of cases	Interventional procedure	Type of imaging guidance			Harm severity (no.) [13]
			Fluoroscopy	US	CT	
Symptomatic or major[a] hemorrhage	9	Biopsy (7) Drainage (1) Neurovascular coiling (1)	1	3	5	Mild (5) Moderate (1) Severe (1) Death (2)
Pneumothorax	3	Biopsy (2) Drainage (1)		1	2	Mild (1) Severe (2)
Thermal injury	2	RFA (2)			2	Moderate (1) Severe (1)
Bowel perforation	2	Drainage (1) RFA (1)			2	Moderate (1) Death (1)
Bowel perforation and splenic injury	1	Drainage (1)		1		Moderate (1)
Nerve damage	1	RFA (1)			1	Severe (1)
Osteonecrosis	1	RFA (1)			1	Moderate (1)

Abbreviations: CT: computed tomography. US: ultrasonography.
[a] Requiring blood transfusion or intervention.

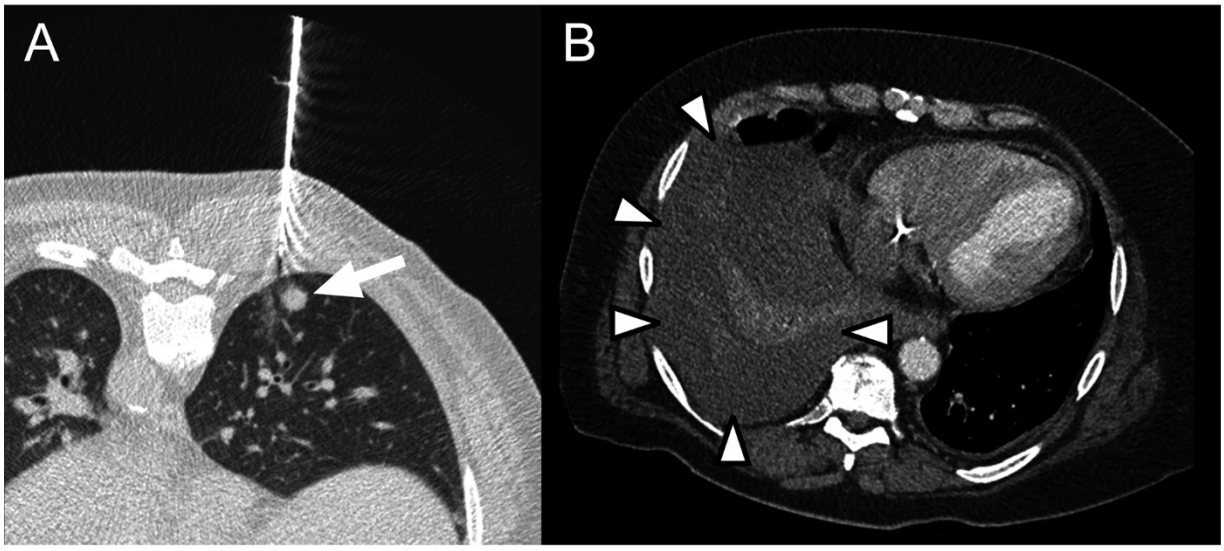

Fig. 2. A 52-year-old man with a history of renal cell cancer underwent CT-guided biopsy of a pulmonary nodule in the right lower lobe (A, arrow) because of the suspicion of metastatic disease. The biopy procedure was initially thought to be uneventful, but a hematothorax developed that became infected (B, arrowheads). The patient eventually underwent video-assisted thoracoscopic surgery to treat the infected hematothorax and was hospitalized for 16 days.

3. Results

3.1. Included cases

A total of 74 cases were submitted to the complication registration system between June 2015 and September 2019. Of these 74 cases, 3 were excluded because they were too poorly reported to understand the nature of the complication, and 4 were excluded because they were not related to any procedure that was performed at the department of radiology. Eventually, 67 cases were included.

3.2. Types of complications and errors

The 67 cases that were included involved diagnostic complications (n = 5), diagnostic errors without any harmful consequences to the patient (n = 28), diagnostic errors with unknown consequences to the patient (n = 1), interventional complications (n = 19), organizational complications (n = 7), and organizational errors without any harmful consequences to the patient (n = 7).

3.3. Diagnostic complications/errors

In the group of diagnostic complications/errors, there were 21 perceptual errors and 13 cognitive errors. This 61.8 % (21/34) perceptual error rate was not significantly different ($P = 0.297$) from the 70 % perceptual error rate that was previously reported in the literature [13]. According to the more refined Kim and Mansfield classification of diagnostic errors in radiology [10], the far majority of diagnostic complications/errors was attributable to underreading (41.2 % [14/34]) and faulty reasoning (23.5 % [8/34]) (Table 2). A representative case example is shown in Fig. 1.

3.4. Interventional complications

In the group of interventional complications, most cases (47.4 % [9/19]) concerned symptomatic or major hemorrhage (Table 3). A representative case example is shown in Fig. 2.

3.5. Organizational complications/errors

In the group of organizational complications/errors, the leading

Table 4
Overview of all 14 organizational complications/errors that were included in this study, according to the ICPS [12], organ system/subspecialty, imaging modality, and harm severity according to the WHO's definition [13].

Incident type according to ICPS [12]	No. of cases	Incident subclassification according to ICPS (no.) [12]	Organ system / subspecialty (no.)	Imaging modality (no.)			Harm severity (no.) [13]
				X-ray	US	CT	
1. Clinical administration	2	Not performed when indicated (1) Incomplete/inadequate (1)	Abdomen (1) Neuro (1)		1	1	None (1) Mild (1)
2. Clinical process / procedure	5	Wrong body part/side/site (5)	Abdomen (1) Cardiothoracic (1) Interventional (3)	1	1	3	None (1) Mild (2) Moderate (2)
3. Documentation	3	Charts/medical records/assessments/ consultations (2) Letters/E-mails/records of communication (1)	Abdomen (1) Cardiothoracic (1) Musculoskeletal (1)	2		1	None (2) Mild (1)
4. Healthcare associated infection	0						
5. Medication / IV fluids	1	Adverse drug reaction (1)	Unknown (1)		1		Moderate (1)
6. Blood / blood products	0						
7. Nutrition	0						
8. Oxygen / gas / vapour	0						
9. Medical device / equipment / property	3	Device/equipment/property list (1) Dislodgement/misconnection/removal (1) Inappropriate for task (1)	Cardiothoracic (1) Interventional (2)	2	1		None (3)
10. Behavior	0						
11. Patient accidents	0						
12. Infrastructure / building / fixtures	0						
13. Resources / organizational management	0						

Abbreviations: CT: computed tomography. US: ultrasonography.

ICPS incident type was clinical process/procedure with wrong body part/side/site as subclassification (35.7 % [5/14]) (Table 4). A representative case example is shown in Fig. 3.

3.6. Harm severities

In the 67 cases that were included, harm severities were none (n = 35), mild (n = 10), moderate (n = 10), severe (n = 6), death (n = 5), and unknown (n = 1). Median harm severity ± interquartile range (using an ordinal 1–5 scale for no, mild, moderate, and severe harm, and death) for diagnostic complications was 4 ± 2, for interventional complications 4 ± 2, and for organizational complications 2 ± 1 (Fig. 4). Harm severity of interventional complications was significantly higher than that of organizational complications ($P < 0.05$). There were no significant differences in harm severities between diagnostic and interventional complications and between diagnostic and organizational complications ($P > 0.05$).

4. Discussion

This study described the concept of a new complication registration system for errors in radiology, and its yield in a tertiary care radiology department in a consecutive 5-year period. Safety event reporting systems have already been in use by several institutions [14–16], but the emphasis of these systems is more on documentation and monitoring of patient safety incidents on a managerial level. One of the novelties of the complication registration system that has been described in the present communication, is the open departmental culture in which all complications are discussed in a standardized manner. Cases were submitted by almost all subspecialty disciplines (except pediatric radiology and nuclear medicine), involved both diagnostic, interventional and organizational complications/errors, and comprised all patient harm severity levels. Therefore, implementation of this complication registration system in a radiology department can be considered feasible.

More than half of submitted cases (50.7 % [34/67]) involved diagnostic complications/errors, and most of them involved perceptual errors (61.8 % [21/34]). The latter was not significantly different from the 70 % perceptual error rate that was previously reported in the literature [9], which suggests that the complication registration system captures diagnostic error cases that are reflective of clinical practice. The underlying causes of perceptual errors remain poorly understood [9]. Poor conspicuity of the target lesion on the image, reader fatigue, an overly rapid pace of performing interpretations, distractions, and satisfaction of search have been reported as risk factors, although most perceptual errors lack an obvious cause [9].

Most of the submitted interventional complications were due to symptomatic or major hemorrhage (47.4 % [9/19]), of which the majority (77.8 % [7/9]) after biopsy. A previous study reported that the incidence of major bleeding after percutaneous biopsies is very low (0.3 %), but that delayed complications (i.e. > 24 h after biopsy) occur in a non-negligible proportion (19 %) of cases [17]. Standardized procedural checklists and reporting protocols for postprocedural care are essential to prevent and minimize bleeding complications [18], and they have already been in use in our hospital before the new complication registration system became operational. In addition, pain has been reported the most common presentation of major bleeding complications [17]. This clinical symptom should prompt the radiologist and referring physician to consider initiating appropriate diagnostic tests and possible subsequent treatment for clinically relevant hemorrhage in a timely manner.

The leading cause of all organizational complications/errors that were submitted, was the performance of a radiologic procedure on the wrong body part, side, or site (35.7 % [5/14]). This emphasizes the necessity for healthcare professionals in the radiology department to consistently comply with the preprocedural verification process, which includes a "time out" before starting the procedure [19,20]. There is one previous study that also classified patient safety incidents in radiology according to the ICPS, but the authors of that study did not report how many errors fell in the wrong body part/side/site subcategory [21].

Documentation and monitoring of interventional complications is already common practice in most modern radiology departments [22]. In the present study, harm severity of interventional complications was

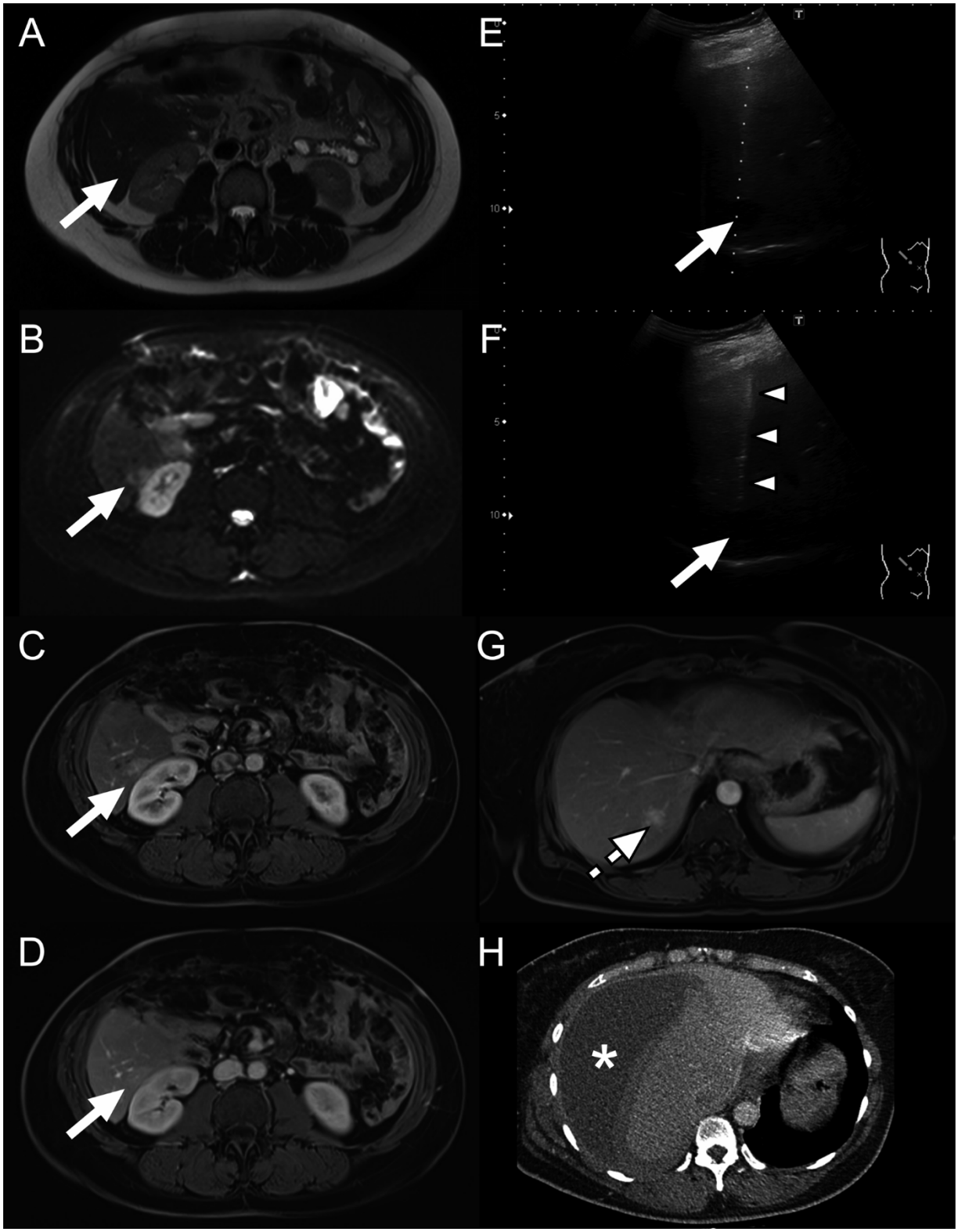

Fig. 3. A 50-year-old woman with Von Hippel–Lindau syndrome and a history of pylorus preserving pancreaticoduodenectomy because of a grade-1 neuroendocrine tumor of the pancreatic head, underwent MRI because of recurrent episodes of pancreatitis. MRI with T2-weighted (A), low b-value (50 s/mm^2) diffusion-weighted (B), late arterial phase (C), and portal venous phase (D) MRI show a lesion in segment 6 of the liver (A-D, arrows) that was not seen on previous imaging. Because of the suspicion of metastatic disease in segment 6 of the liver, ultrasound-guided biopsy was performed. Representative ultrasonographic images show the planned biopsy path towards the lesion (E, arrow) and the biopsy needle (F, arrowheads) just in front of the lesion (F, arrow). Afterwards, it was realized that a lesion in segment 7 of the liver was erroneously biopsied, instead of the lesion in segment 6 of the liver. Portal venous phase MRI shows the erroneously biopsied lesion in segment 7 of the liver (G, dashed arrow) that was unchanged compared to previous imaging and that was thought to represent a hemangioma (pathology revealed focal nodal hyperplasia). Directly after biopsy, the patient developed a large subcapsular hematoma that required blood transfusion. The subcapsular hematoma became infected and was surgically treated. Because of the post-biopsy complications, the patient was hospitalized for 16 days, including 10 days intensive care admission.

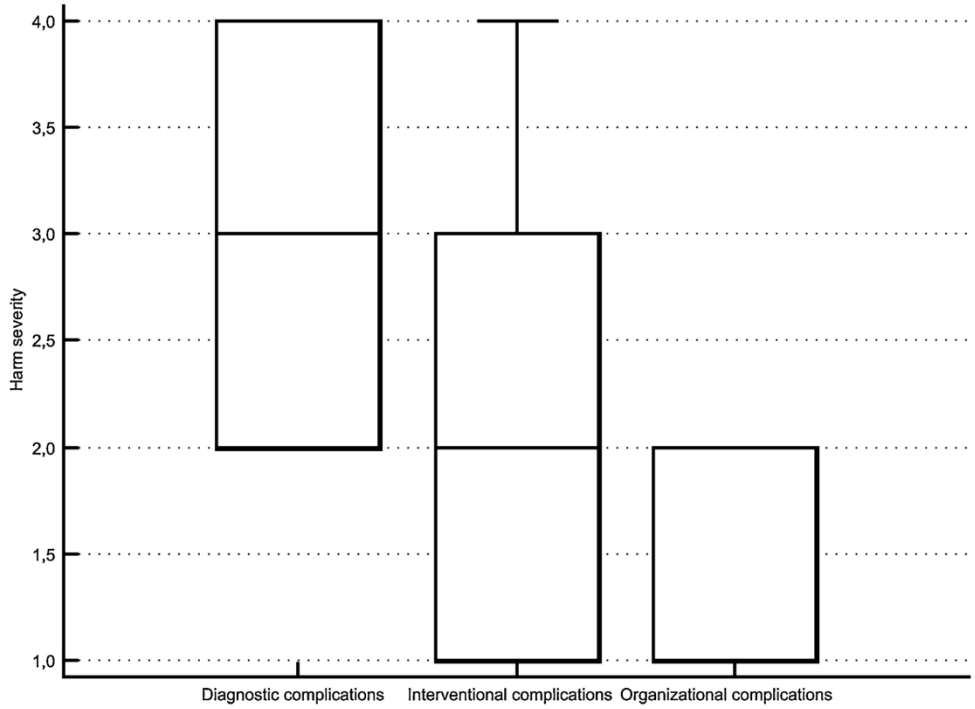

Fig. 4. Box and whisker plot showing harm severities for diagnostic, interventional, and organizational complications.

significantly higher than that of organizational complications, which may be due to the potentially more direct negative effects of interventional errors on a patient's health than organizational errors. Nevertheless, harm severities of several of the organizational complications were non-negligible. Interestingly, harm severity of diagnostic complications was statistically equal to that of interventional complications in this preliminary series. Although future studies with larger sample sizes are required, these findings underline the importance of a departmental system that addresses all groups of radiologic complications rather than interventional complications only.

This study had some limitations. First, the results of this study are applicable to a tertiary care center and may not be translatable to non-academic institutions. Second, it was not possible to determine how many radiologists and residents submitted cases to the complication registration system due to its anonymous nature. Therefore, the participation rate is unclear in this respect. Third, it remains unclear if the number of future errors can be reduced with a complication registration system as described in the present study. A potential disadvantage may be hypervigilance for future errors, which may induce defensive medicine practices. This requires further investigation.

In conclusion, it is feasible to implement the new complication registration system for radiologic errors that was described in this study. Perceptual mistakes, hemorrhage, and procedures on the wrong body part/side/site dominate in the categories of diagnostic, interventional, and organizational complications/errors, and these should be the topic of vigilance in clinical practice and further research. Future studies are required to determine whether this new complication registration system reduces radiologic errors and improves healthcare quality.

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IRB statement

- This retrospective study used publicly available data and did not involve the investigation of human subjects requiring institutional review board approval.

- This study has been performed in accordance with the ethical standards in the 1964.

Declaration of Helsinki

-This study has been carried out in accordance with relevant regulations of the US Health Insurance Portability and Accountability Act (HIPAA).

CRediT authorship contribution statement

Marco Carrara: Data curation, Formal analysis, Investigation, Methodology, Project administration, Visualization, Writing - original draft, Writing - review & editing. **Derya Yakar:** Conceptualization, Formal analysis, Investigation, Methodology, Visualization, Writing - original draft, Writing - review & editing. **Ömer Kasalak:** Conceptualization, Formal analysis, Investigation, Methodology, Writing - original draft, Writing - review & editing. **Thomas C. Kwee:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Visualization, Writing - original draft, Writing - review & editing.

Declaration of Competing Interest

None.

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